UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,741	01/03/2006	John Foekens	47675-93	8977

22504 7590 12/20/2007

DAVIS WRIGHT TREMAINE, LLP/Seattle
1201 Third Avenue, Suite 2200
SEATTLE, WA 98101-3045

EXAMINER	
MYERS, CARLA J	
ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,741	FOEKENS ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

> Group I, claims 1-24, 39 and 45-77 (in part), drawn to methods for predicting responsiveness of a subject with a breast tissue proliferative disorder to a therapy by assaying for methylation status.
>
> Group II, claims 25-38 and 40-44, drawn to nucleic acids, sets of oligonucleotides and arrays comprising said nucleic acids and arrays.
>
> Group III, claim 39 (in part), drawn to a method for detecting a single nucleotide polymorphism.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the claimed inventions do not share a special technical feature because the feature linking the claimed inventions was known in the art at the time the invention was made. In particular, the concept of detecting the occurrence of breast cancer by assessing the

methylation status of a marker gene, including the PITX2 gene, was known in the art at the time the invention was made. For example, Issa, J.P. (WO 01/019845; page 7, 11 and 29) discloses determining the methylation status of the PINX1 gene in breast cancer tissue as predictive of the occurrence (and thereby the response to treatment) of breast cancer. Nucleic acids whose methylation status is predictive of breast cancer and thereby response to breast cancer therapy were also known at the time the invention was made. For example, Issa also teaches nucleic acids comprising 18 nucleotides of STX1 sequences, including SEQ ID NO: 23 therein which is identical to nucleotides 2035-2057 of present SEQ ID NO: 411 and SEQ ID NO: 24 therein which is identical to nucleotides 225-2246 of present SEQ ID NO: 411. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

3. **Further restriction requirement applicable to invention I**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

STMN1, SFN, S100A2, TGFBR2, TP53, PTGS2, FGFR1, SYK, PITX2, GRIN2D, PSA, CGA, CYP2D6, MSMB, COX7A2L, VTN, PRKCD, ONECUT2, WBP11, CYP2D~ DAG1, ERBB2, S100A2, TFF1, TP53, TMEFF2, ESR1, SYK, RASSF1, PITX2, PSAT1, CGA,and PCAF

Applicant is required, in reply to this action, to elect one gene or one particular combination of genes to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected

species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 1-24 and 45-77 encompass the species recited above.

The following claim(s) are generic: NONE

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited genes consists of a distinct nucleotide sequence and encodes for a protein having a different biological activity and effect. Accordingly, the recited genes do not share both a common structure and function.

4. **Further restriction requirement applicable to invention I**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are each of the target nucleic acid sequences recited in claims 15-19, 39 and 45-77.

Applicant is required, in reply to this action, to elect one or a particular combination of target nucleic acid sequences to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Note that this election must be commensurate with the election of a particular gene or combination of genes.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 15-19, 39 and 45-77 encompasses the species recited above.

The following claim(s) are generic: claims 1-14, and 20-24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited target nucleotide sequences consists of a distinct nucleotide sequence and encodes for a protein having a different biological activity and effect. Accordingly, the recited target nucleotide sequences do not share both a common structure and function.

5. **Further restriction requirement applicable to invention I**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are each of the oligonucleotides recited in claims 50-54, 55-56 (i.e., the oligonucleotides of claims 30-35), and 59-60.

Applicant is required, in reply to this action, to elect a single oligonucleotide or a particular combination of oligonucleotides to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Note that this election must be commensurate with the election of a particular gene or combination of genes and the election of particular target nucleic acid sequences or combinations thereof.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 50-56 and 59-60 encompasses the species recited above.

The following claim(s) are generic: claims 1-24, 39, 45-49, 57, 58 and 61-77.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The recited oligonucleotides differ from one another with respect to their nucleotide structure and their hybridization specificity. The oligonucleotides thereby have a different chemical structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

6. **Further restriction requirement applicable to invention II**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are each of the nucleic acid molecules and oligomers consisting of the sequences recited in claim 25.

Applicant is required, in reply to this action, to elect a nucleic acid molecule or a particular combination of nucleic acid molecules to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Note, for example, that if Applicants elect only one oligonucleotide, then the combinations/sets of oligonucleotides recited in claims 36-38 will not read on the elected invention and will be withdrawn from consideration.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 25-38 and 40-44 encompass the recited species.

The following claim(s) are generic: NONE.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited nucleic acids and oligonucleotides differ from one another with respect to their nucleotide structure and their hybridization specificity. The nucleic acids and oligonucleotides thereby have a different chemical structure and different biological activity. Thus, the claimed oligonucleotides do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

7. **Further restriction requirement applicable to invention II**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are each of the nucleic acid molecules recited in claim 40.

Applicant is required, in reply to this action, to elect a nucleic acid molecule or a particular combination of nucleic acid molecules to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Note that this election must be commensurate with the election of a particular nucleic acid and oligonucleotide, or combination of nucleic acid and oligonucleotide, as set forth in paragraph 6 above.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 40-44 encompass the recited species.
The following claim(s) are generic: claims 25-38

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited nucleic acids differ from one another with respect to their nucleotide structure and their hybridization specificity. The nucleic acids thereby have a different chemical structure and different biological activity. Thus, the claimed nucleic acids do not have both a

"common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

8. **Further restriction requirement applicable to invention III**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are each of the nucleic acid molecules recited in claim 39: SEQ ID NO: 27, 40, 122, 43, 74, 127, 86, 90, 128, 105, 115, 121, 126, 129, 125, 132, 122, 123, 131, 127, 130, 124 and 128.

Applicant is required, in reply to this action, to elect a nucleic acid molecule or a particular combination of nucleic acid molecules to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 39 encompass the recited species.
The following claim(s) are generic: NONE

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited nucleic acids differ from one another with respect to their nucleotide structure and their hybridization specificity. The nucleic acids thereby have a different chemical structure and different biological activity. Thus, the claimed nucleic acids do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634